AUG 1 2 2005

K051129

510 (K) Summary

SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Submitter Information:

Company:	INNOVA VISION INC. No. 231-1, Wen-Te Road, Chiung-lin Village, Hsin-Chu County, Taiwan.
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Date Prepared	15 Apr. / 2005

Identification of Device:

Classification Name:	Soft hydrophilic contact lens, per 21 CFR. 886.5925
Trade Name:	Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Common or usual Name:	Soft (hydrophilic) Contact lens (daily wear)
FDA Classification:	Class II
Registration Number	3003746024

Predict Device:

SuperView (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear (K033136)-made from Innova Vision Inc., Taiwan.

ACUVUE (etafilcon A) Contact Lens Visibility tint (K962804) -made from Johnson & Johnson Co. USA.

Indications for Use:

Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear is indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are myopia or hyperopia and may exhibited refractive astigmatism up to 2.00 diopters that does not interfere with visual acuity. The eye care practitioner may prescribe the contact lens for frequent replacement wear, with cleaning, rinsing and disinfection and scheduled replacement. The contact lens may be disinfected using a chemical (not heat) disinfection system only.

Description of Device:

Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear are available as non-spherical lenses manufactured by spin-casting method. The model illuminated with high water content (58 %). The hydrogel lens' material is a random copolymer composed of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid (MAA), which was cross-linked with 1,1,1-trimethylolpropane trimethacrylate (TMPTMA) and Ethylene Glycol Dimethacrylate (EGDMA) via UV photo- polymerization. The Discon Contact lens with visible tint is tinted blue using Reactive Blue Dye #19 to make the lens more visible for handling. Lenses are supplied sterile in sealed blister packers containing sterile isotonic phosphate buffered saline. The compatibility and package integrity of the blister pack packaging system has been demonstrated and successfully used for other marketed lens products, and packaged lenses are effectively steam-sterilized in a validated autoclave.

Summary of Clinical Study:

The Discon Lenses were tested in 65 human eyes separately within 6 months. Nearly a hundred percent of the participants' vision was corrected and nearly all were satisfied with the lens wearing and care of lenses. In general, these products are good and safe for customers.

Discon lenses have been wide-used around the world, including Taiwan, China, Europe, etc. Among the users being daily worn the Discon lenses, all the procedures were in generally stable condition without severe complication. There are no significant side effects and complaints to be observed.

Nonclinical Studies:

A series of nonclinical performance tests were performed to demonstrate the safety and effectiveness of the Discon Soft Contact lens, and establish substantial equivalence to predicate lenses-SuperView Lens (K033136); ACUVUE Lens (K962804). All testing was conducted in accordance with the May 1994 FDA guideline titled *Premarket Notification 510(K) Guidance Document for Class IV Contact lenses,* and in conformance to applicable device regulations. The evidence of substantial equivalent to the predicate lens described as follow:

a) Technological characteristics studies

Discon contact lens designs in the following parameter ranges:

Diameter range; 13.8 to 14.2 mm

Power range: +6.00D to –12.00D

Center thickness: varies with power (0.08 to 0.12 mm for –3.00D)

Lenses have the following properties:

Refractive index: 1.407 (hydrated)

Light transmittance: >93%

Water content: 56 to 60 %

Oxygen permeability (edged corrected) : 24×10^{-11} [(cm^2/sec)(ml O_2/ml-mmHg)] @ 35℃

There characterizations of Discon Contact lenses are equivalent and comparable to those of predicate lenses.

b) Biocompatibility

In accordance with the May 1994 Guidance Document for daily wear contact lenses, toxicity studies have been conducted on the model: Discon Contact lenses. The Irritation test in the rabbit eye and Systemic toxicity studies indicate the extracts would be considered as non-toxic and nor irritated. The Cytotoxicity testing demonstrates the lens is not cytotoxic under the conditions of the study.

c) Microbiology

Steam sterilization process has been validated to deliver a minimum SAL of 10^{-6}, thereby complying with the requirement of FDA Group IV. There is shelf-life stability data supporting that the lens remains sterile through the expiration date claimed for the product.

d) Leachability

Studies were conducted to determine the leachable materials from the finished lens. The results show that, at the levels of the detection reported, there are no leachable monomers and addictive residues.

Substantial equivalence Statement:

Testing performed on the Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear indicated that it can support the efficiency and security use as well as the predicate devices- SuperView (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear (K033136) & ACUVUE (etafilcon A) Contact Lens visibility tint-K962804), when used in accordance with the instructions for use. It is due to the facts that The risks and benefits of the subject device are the same as soft contact lenses for to the daily wear.

In conclusion, it is Innova's conviction that data submitted in this 510(k) to validate the claim of substantial equivalency, substantiates our ability to manufacture a soft contact lens, the Discon Soft (hydrophilic) Contact Lens for Daily Wear, with the same established safety profile and effectiveness as the predicate device--SuperView (polymacon) Soft (hydrophilic) Contact Lens for Daily Wear (K033136) & ACUVUE (etafilcon A) Contact Lens visibility tint (K962804).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

Innova Vision, Inc.
c/o Ms. Jennifer Reich
Harverst Consulting Corp.
3892 South America West Trail
Flagstaff, AZ 86001

Re: K051129
Trade/Device Name: Discon (etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: July 11, 2005
Received: July 13, 2005

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K051129

Device Name: Discon (Etafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Indications for Use:

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The eye care practitioner may prescribe the contact lens for frequent replacement wear, with cleaning, rinsing and disinfection and scheduled replacement. The contact lens may be disinfected using a chemical (not heat) disinfection system only.

Prescription Use X OR Over-The-Counter _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K051129